MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-102349-PIP01-26-M01

Scope of the Application

Active Substance(s)

CANGRELOR

Condition(s)

Prevention of non-site specific embolism and thrombosis

Pharmaceutical Form(s)

Powder for concentrate for solution for injection/infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Chiesi Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Chiesi Ltd submitted to the licensing authority on 16/02/2026 10:43 GMT an application for a Modification

The procedure started on 17/02/2026 16:15 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-102349-PIP01-26-M01

Of 13/05/2026 12:44 BST

On the adopted decision for CANGRELOR (MHRA-102349-PIP01-26-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for CANGRELOR, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Chiesi Ltd, 333 Styal Road, Manchester, UNITED KINGDOM, M22 5LG

ANNEX I

1. Waiver

1.1 Condition:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of non-site specific embolism and thrombosis

2.2 Indication(s) targeted by the PIP:

Prevention of thrombotic events in paediatric patients undergoing diagnostic and/or therapeutic percutaneous vascular procedures.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	2	Measure 1: Two staged study with an in vivo humanised mouse model and confirmatory in vitro study to determine a complete concentration response of cangrelor. Measure 2: Analysis of mechanism behind kidney toxicity in rat and dog and relevance for human in general and for children below 1 year of age in particular.
Clinical Studies	2	Measure 3: This measure was deleted during procedure MHRA-102349-PIP01-26-M01. Study 4: (MDCO-CAN-15-01) (This study was added during procedure MHRA-102349-PIP01-26-M01.) A prospective, open-label, single-arm, multi-centre study to assess the pharmacokinetics/ pharmacodynamics (PK/PD) and safety of different cangrelor doses in neonatal subjects at risk of thrombosis. Study 5: (CLI-06727AA1-03) (This study was added during procedure MHRA-102349-PIP01-26-M01.) A prospective, open-label, non-randomised, multicentre trial to assess the safety and pharmacodynamics of cangrelor as procedural platelet inhibitor in paediatric subjects undergoing percutaneous vascular procedures.
Extrapolation, Modeling & Simulation Studies	4	Study 6: (ICx-B206 – M&S1 – Step 1) (This study was added during

		procedure MHRA-102349-PIP01-26-M01.) Population pharmacokinetic-pharmacodynamic modelling in adult subjects Study 7: (ICx-B206 – M&S1 – Step 2) (This study was added during procedure MHRA-102349-PIP01-26-M01.) Population pharmacokinetic-pharmacodynamic modelling in adult subjects Study 8: (ICx-B206 – M&S2 Step 1 and 2) (This study was added during procedure MHRA-102349-PIP01-26-M01.) Updated PK model after integration of 2 additional datasets in adults Study 9: (ICx-B206 – M&S2 – Step 3 and 4) (This study was added during procedure MHRA-102349-PIP01-26-M01.) Updated PK model after integration of 2 additional datasets in adults Extrapolation Plan Studies 4, 5, 6, 7, 8 and 9 are part of the extrapolation plan of efficacy and safety data from adults, adolescents and paediatric patients to the paediatric population from birth to less than 18 years of age for the Prevention of non-site specific embolism and thrombosis.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/06/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes